510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	December 14, 2012
Submitter:	NeoSoft, LLC N27W23910A Paul Road Pewaukee, WI 53072 FDA Registration Number: NA
Primary Contact Person:	Jackie Schwabe Director of Innovation NeoSoft, LLC Phone (262) 522-6120 Fax (262) 347-1251
Secondary Contact Person:	Tim Roloff Quality Engineer NeoSoft, LLC Phone (262) 522-6120 Fax (262) 347-1251
Device: Trade Name:	suiteHEART
Common/Usual Name:	System, image processing, radiological- Picture archiving and communications system.
Classification Names:	21CFR 892.2050
Product Code:	LLZ
Predicate Device:	
Predicate Device Name:	CardiacVX
Predicate 510k Number:	K121762
Predicate Manufacturer:	GE Medical Systems

Device Description:

suiteHEART is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. suiteHEART can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in cine mode to facilitate visualization.

Measurement tools on the report interface include: point, distance, area, and volume measurements (including ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements). Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, T2 Star analysis, and patent foramen ovale (PFO) analysis.

Indications for Use:

The NeoSoft, LLC suiteHEART for MRI is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. suiteHEART can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows the access to studies and series of multi-slice, multiphase images. Multi-phase sequences of images can be displayed in a cine mode to facilitate visualization.

A report input interface is also available. Measurement tools on the report interface make it possible to quickly and reliably fill out a complete clinical report of an imaging exam. Available tools include: point, distance, area, and volume measurement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, and T2 Star analysis.

The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians. When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

Technology:

The proposed medical device, suiteHEART, employs the same fundamental scientific technology as its predicate device CardiacVX. The proposed device (suiteHEART) is substantially equivalent to the predicate device because it is a post-processing software option for use on cardiac MR image datasets.

Determination of Substantial Equivalence:

Summary of Non-Clinical Tests:

suiteHEART complies with the following voluntary standards: ISO 14971 - Medical devices-Application of Risk management to medical devices, IEC 62304 - Medical device software – Software life cycle processes, and NEMA PS 3.1 - 3.20 (2011), Digital Imaging and Communications in Medicine (DICOM). The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Integration testing (Verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

Summary of Clinical Tests:

The MR acquired clinical images that were used for the completion of verification and validation testing for suiteHEART was obtained from East Side Medical Radiology, LLC and other third-party facilities under the provisions of a nonsignificant risk investigation for internal volunteer scanning. In addition, multi-vendor anonymized MR contrast-enhanced images were obtained from a third- party clinical research study.

Conclusion:

NeoSoft, LLC considers the suiteHEART application to be as safe, as effective, and performance is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 20, 2013

Ms. Jackie Schwabe
Director of Innovation
NeoSoft, LLC
N27 W23910A Paul Road
PEWAUKEE WI 53072

Re: K130228
Trade/Device Name: suiteHEART
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 21, 2013
Received: February 4, 2013

Dear Ms. Schwabe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130228

Device Name: suiteHEART

Indications for Use:

suiteHEART is an analytical software tool, which provides reproducible tools for the review and reporting of medical images. suiteHEART can import medical images from a MR system and display them in a viewing area on the computer screen. The viewing area allows the access to multiple studies and series of multi-slice, multi-phase images. Multi-phase sequences of images can be displayed in a cine mode to facilitate visualization.

A report input interface is also available. Measurement tools on the report interface make it possible to quickly and reliably fill out a complete clinical report of an imaging exam. Available tools include: point, distance, area, and volume measurement tools such as ejection fraction, cardiac output, end-diastolic volume, end-systolic volume, and volume flow measurements.

Semi-automatic tools are available for left ventricular contour detection, valve plane detection, vessel contour detection for flow analysis, signal intensity analysis for myocardium and infarct sizing measurement, and T2 star analysis.
The results of the measurement tools are interpreted by the physician and can be communicated to referring physicians.

When interpreted by a trained physician these tools may be useful in supporting the determination of a diagnosis.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health

510(k) K130228